ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

Location of Meeting
Frontier Building, 3601 C Street, Room 890/896

FINAL - MINUTES OF MEETING
November 18, 2011
8:00 a.m.

Committee Members Present:
Dharma Begich, Pharm.D.
Marvin Bergeson, MD
Richard Brodsky, MD
Robert H. Carlson, MD
Jeffrey Demain, MD
Mary Elizabeth Gardner, ANP
Vincent Greear, R.Ph.
Daniel P. Kiley, DDS MPH
William McCormick, Pharm.D.
John Pappenheim, MD
Claudia Phillips, MD
Jill Reid, R.Ph. (telephonic)
John Riley, PA
Trish White, R.Ph. (telephonic)

Committee Members Absent:
Amber L. Briggs, Pharm.D.
Diane Liljegren, MD
Paul Michaud, Pharm.D.

Others Present:
Chad Hope, Pharm.D.
Julie A. Pritchard, Pharm.D.
Flora Solomon
C.J. Kim

1. Call to Order – Chair

Chair Brodsky called the meeting to order at 8:02 a.m.

2. Roll Call

A quorum was present.

3. Public Comments - Local Public/Health Practitioners

Dr. Christine Goddard, a staff psychiatrist at Anchorage Community Mental Health Services discussed Vivitrol. We primarily partner with the Department of Corrections in serving their population after they are released. This population has co-occurring illnesses including severe poly dependency, persistent debilitating mental illness, very aggressive, and largely resistant to Neuroleptic for treating psychotic disorders. We have data that suggests 60% are addicted, primarily to alcohol, but also to opiates. In partnering with the Department of Corrections, we ask that the patients be put on Neltrexon initially to ensure they can tolerate it and then we immediately transition them to Vivitrol when they are released. Vivitrol seems to bring the patients great relief and reduced cravings. Many of these

patients have spent a lot of time in prisons and state hospitals. They often have difficulties with their families, social skills, have a long history of trauma, and do not cope well. As I do not want to setup them up for failure, I try to find the cheapest, most effective medication available. They are often heavily addicted to drugs and alcohol. They often cheek their medications to sell or trade with others as a sport. Our biggest problem is getting the medication into their system. If that can be accomplished, we have a chance of maintaining them in housing or preventing them from being remanded back to prison. After serving in prison, many have been able to interrupt their behavior, calm down, get away from negative influences, and are motivated to get off alcohol, which has ruined their lives. I would like the opportunity to prescribe them Vivitrol. There is a great team effort at the mental health center in wraparound services for housing, skills training, and various support groups. This is a great opportunity for us, along with our partners, to make a huge impact on the state of Alaska.

In response to Dr. Hope, Dr. Goodard said the Department of Corrections did not prescribe Vivitrol before an inmate's release. We work to get Medicaid benefits for inmates before they are released so they can get medication. We have talked about having a parole officer bring an inmate to the mental health center so they can get an injection and then returning them to prison, but there is not yet a mechanism within the system to do that.

DR. LEON CHANDLER: An Alaska physician for the last 41 years, said he was on the Drug Utilization Committee when it was first formed, so he recognizes the committee's need and burden. However, I am speaking on behalf of patients who have chronic injuries and have to live the rest of their lives with chronic pain. From an economic and social standpoint, a physician access to narcotic pain medication should not be limited. Many medications are limited due to cost, patent issues, and the fact that they are new to the market. The patients that we treat are all unique. A medication does not necessarily work for a patient just because a book says it will. The specific orphan drugs that show up for specific causes are not cost effective and we use special drugs when necessary. The limitations that Medicaid puts on us, and the time we spend on the phone trying to meet the criteria to authorize the drugs needed, is not cost beneficial. It is amazing that a pharmacist will allow me to write a prescription for a 1,000-milligram table three times a day, but not a 2-milligram tablet six times a day. The half-life of these medications is broken down at various times and is needed in different systems and modalities for administration. We are the experts. When we ask for something, it is not to bilk the system, but because each patient is unique and needs help. I would like help in breaking through the barriers to be more cost effective. I am not sure what that system would be, but there is a very thin balance between economic and social issues.

JIM GOTTSTEIN: The president of the Law Project for Psychiatric Rights, discussed the pediatric use of psychotropic medications, particularly related to medically accepted indications. Under Medicaid statute, drugs are only properly reimbursable if they are for a medically accepted indication, which means indications approved by the FDA or court-supported by citations in one of three drug references. We have prepared a chart of pediatric use of medically accepted indications, which are available on our website at psychrights.org. My concern is the great proliferation in the use of psychotropic drugs in children, which causes harm and has little scientific support, but is what Congress relied on for its limited coverage. Two books should be read by every doctor, Anatomy of an Epidemic by Robert Whittaker, which describes the societal impact of the expansion of psychotropic drugs by expanding the number of people on disability rolls, and The Myth of a Chemical Cure by Joanne Moncrieff.

4. Re-review of SSRIs (Red Category)

JENNIFER TOTTEN: A representative of Forest Research discussed Vilazodone (Viibryd), a new medication approved for the treatment of major depressive disorder in adult patients. Viibryd binds with selectivity and high affinity to the serotonin transporter. It is a serotonin reuptake inhibitor. It also binds with affinity to the serotonin 1-A receptor. It is a serotonin 1-A receptor partial agonist. Two trials and their outcomes were reviewed. Like other antidepressants, Viibryd has a boxed warning for the risk of suicidality. It is not approved for use in pediatric patients. Use of Viibryd with an MAOI or within 14 days of stopping or starting an MAOI is contraindicated. Please see the full prescribing information for additional warnings and precautions, which are similar to other antidepressants. Viibryd is a pregnancy category C. Women who are pregnant or lactating should only use Viibryd if the benefits outweigh the risks. There are no dosage adjustments required in elderly patients, patients with renal impairment, or patients with mild to moderate hepatic impairments. Viibryd has not yet been studied in patients with severe hepatic impairment. The recommended doses were reviewed. It should also be taken with food as taking it on an empty stomach can affect the drug concentrations.

Dr. Pritchard gave the Magellen presentation on SSRIs. Drugs in this class have varying FDA approved indications. They are classified overall as antidepressants, although indicates do include OCD, panic disorder and bulimia nervosa. Women generally have a higher incidence of depression than men do. It has been said that 8.3% of adolescents, ages 12 to 17, also experience bouts of depression. In 2010, the American Psychiatric Association published treatment guidelines for major depressive disorder or MDD. SSRIs are the optimal choice for most patients and there is no significant evidence of superior efficacy with any other drug class. SSRIs may increase risk of bleeding. SSRIs should be used with caution in seizure patients. Doses should be tapered down and not abruptly discontinued. In October, there were 3,147 claims: 24.59% for Sertraline tablets, 23.6% for Fluoxetine capsules, and 21.16% for Lexapro. At the last review, a motion for class effect passed unanimously. Significant changes include Viibryd became available for MDD. Viibryd is 96 to 99% protein bound and has a half-life of 1.04 days with linear pharmacokinetics. It is available as 10, 20 and 40-milligram tablets and should be taken with food. Sertraline oral concentrate is contraindicated with Disulfiram due to the alcohol content of the liquid. Citalopram should not be dosed at higher than 40 milligrams per day due to the risk of QT prolongation. Fluoxetine has been associated with midrisis and should be used with caution in patients with increased intraocular pressure.

Dr. Pappenheim discussed the differences between class effect and therapeutic alternatives. Viibryd should be available on the PDL due to its beneficial therapeutic profile. Dr. Brodsky felt there needed to be more comparative trials with Viibryd, rather than placebo, before a clear advantage could be shown. Dr. Phillips said Viibryd did not have enough breakouts to be different from the other SSRI, although it may have fewer sexual side effects. The medically necessary clause can be utilized.

DR. PAPPENHEIM MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED WITH ONE OPPOSED.

5. Re-Review of Short Acting Narcotic Analgesics (Red Category)

LAURA LITZENBERGER: A representative of Janssen Scientific Affairs discussed Tapentadol (Nucynta). Nucynta is indicated for the treatment of moderate to severe pain. It is a schedule 2 opioid. Nucynta is different from other opioids in the fact that it binds to opioid receptors, but also inhibits the

reuptake of norepinephrine. Due to its second mechanism, less of its pain action is solely dependent on opiods, causing different amounts of GI side effects. Several clinical trials and their outcomes were reviewed. Due to the second mechanism of action, we believe that Nucynta provides an additional option to patients with acute pain. It is currently on the formulary of Alaska Regional Hospital and Providence Systems. We would like Nucynta to be available for the Medicaid recipients in Alaska.

Dr. Pritchard gave the Magellen presentation on Short Acting Narcotic Analgesics. Letters from Dr. Brian Coreno and Dr. Doug Vermillion supporting Nucynta was read into the record. Drugs in this class produce supraspinal analgesia, resulting in respiratory depression, euphoria, and physical dependence. In general, opioids are contraindicated in patients with acute or severe bronchial asthma and those with paralytic ileus. Caution should be used when using other agents in this class in those with acute or several bronchial asthma. Doses should be adjusted for patients with renal or hepatic impairment when using any agent in this class. Tramadol agents used in the presence of SSRIs, SNRIs, MAOIs, and tricyclics can increase risk of seizures in serotonin syndrome. The side effect profiles, drug interactions, and uses vary. Please see the package insert for individual drugs in this class. Abrupt discontinuation can result in withdrawal symptoms so the drug should be tapered down. In October, there were 5,866 claims: 50.87% for Hydrocodone with Acetaminophen, 16% for Oxycodone with Acetaminophen, and 10.65% for Tramadol. Significant changes include some patients may rapidly metabolize Codeine due to a specific CYP2D6 phenotype and may convert Codeine to Morphine quickly, resulting in increased serum levels and may experience symptoms of overdose even at regular dosing. Last year, Tramadol was separate from the short-acting agents. In the last review, a motion to include least one short-acting preparation passed unanimously. For the short-acting narcotics, a motion for class effect passed unanimously. The C-2s are on prior authorization and there are no preferred agents for that class.

Dr. Demain said he did not use these drugs in his practice, but often saw problems with them. He questioned if there was an advantage to using Nucynta in patients with mass degranulation syndrome, hives, or other allergic reactions to opioids. It was reported that Nucynta had a significant decrease in side effects, but page 12 of the materials show a higher number than the average. Dr. Brodsky said he was not aware of any clinical benefit other than the proposed lesser GI side effects as outlined by the manufacturer versus what was in the packet. The committee discussed the drugs in the class that required prior authorization. It was noted that the medically necessary clause did not override the prior authorization requirement.

Dr. Demain noted that Meperidine oral and Propoxyphene had been removed from hospital formularies and were no longer available.

DR. DEMAIN MOVED A CLASS EFFECT. SECONDED BY DR. GARDNER. THE MOTION PASSED WITH ONE OPPOSED.

6. Re-Review of Atypical Antipsychotics (Red Category)

ELHAM TABARSI: A representative of Astra Zeneca, said that there was new data reported for Seroquel IR or XR since the last review, but she was available for questions. There were no questions.

DR. KIMBERLY LAUBMEIR: A representative of Bristol-Meyers Squibb discussed Aripiprazole (Abilify). Aripiprazole has 14 FDA approved indications in both adult and pediatric populations,

which were reviewed. It has a unique pharmacology relative to other atypicals. Specifically, it is the first and only dopamine partial agonist. The efficacy of Aripiprazole is thought to be mediated through a combination of partial agonist activity at D2, D3 and 5-HT-1 receptors, and antagonist activity at 5-HT-2 receptors. Several studies and their outcomes were reviewed. Aripiprazole has two boxed warnings including increased mortality in elderly patients with dementia related psychosis and suicidality in antidepressant drugs. The complete boxed warnings and additional information is available on the package insert, as well as on our website at abilify.com. Aripiprazole has the broadest range of indications among the atypical antipsychotics across adult and pediatric populations. Given this breadth of indications and the information provided today, we respectfully request that Aripiprazole remain preferred on the Alaska PDL.

PATRICK HARVEY: A representative of Sunovian Pharmaceuticals discussed Lurasidone (Latuda). Latuda was launched in February of 2011. It is one of the first and only atypical antipsychotics that received first-cycle approval by the FDA based on its efficacy, safety, and tolerability. Several studies and their outcomes were reviewed. We have a safety database comprised of more than 2,000 patients. Compliance and adherence in this class is a major concern in the treatment of schizophrenia. Latuda has the benefit of being dosed once a day with food. It is available in a 40- and 80-milligram tablet. The dosing recommendations were reviewed. There is no dose titration and patients can be started on 80 milligrams if the physician feels it is warranted. This agent is pregnancy category B, whereas all others are pregnancy category C, with the exception of Clozapine. The most commonly observed side effects, which are similar to the other drugs in the class, were reviewed. Overall, about 9.4 %of the patients treated with Latuda discontinued treatment based on side effects, compared to 5.9% taking placebo. It is contraindicated with the use of strong CYP3A4 inhibitors. It carries similar boxed warnings of all atypical antipsychotics, with the exception of the QTC prolongation. Two studies that were still in the process of being peer reviewed and published were reviewed.

LAURA LITZENBERGER: A representative of Janssen Scientific Affairs discussed Risperdal Consta and Invega Sustenna. Risperdal Consta is indicated for the maintenance treatment of schizophrenia and bipolar disorder. It is given as an injection every 14 days. Several studies and their outcomes were reviewed. Invega Sustenna is indicated for acute and maintenance treatment of schizophrenia. It is given by injection every 28 days. It requires no oral overlap, because of the initiation doses. You give a dose on day one, a second dose on day eight, and then 28 days thereafter. Several studies and their outcomes were reviewed. There is no difference between the two drugs.

In response to Dr. Hope, Ms. Litzenberger said including both Risperdal Consta and Invega Sustenna on the PDL would provide physicians with options. The differences in the side effects between the two drugs, as well as the others in the class, were reviewed. Risperdal Consta and Invega Sustenna are two of the three long-acting injections.

Dr. Pritchard gave the Magellen presentation on Atypical Antipsychotics. Two letters from Mental Health America and the National Council for Community Behavioral Health Care supporting the inclusion of all FDA approved antipsychotics, without prior authorization, on the PDL were read into the record.

Dr. Brodsky noted that the P&T Committee does not develop prior authorizations, only the preferred drug list. All medications are available by utilizing the medically necessary clause.

Dr. Pritchard continued her presentation. Indications for agents in this class vary and include schizophrenia, bipolar disease, psychotic disorders treatment, resistant depression, and irritability associated with autistic disorder. The first generation antipsychotics work by blocking the dopamine or D2 receptors in the mesolimbic dopamine pathway, thereby decreasing the positive symptoms associated with psychosis. Second generation agents are serotonin dopamine antagonists. They have a reduced incidence of EPS, lesser impact on prolactin levels, and an increased efficacy on negative symptoms. Their higher affinity for certain receptors are not without adverse effects such as those occurring with metabolic changes. Clozapine and Latuda are pregnancy category B and the others in the class are pregnancy category C. In October, there were 4,261 claims for oral medications and 40 claims for the injectables, for a total of 4,301 claims. The top three oral medications were: 22% for Abilify, 21.5% for Seroquel, and 20.5% for Risperidone tablets. For the injectable class: 77.5% for Risperdal Consta, 10% for Fluphenazine, and 5% for Zyprexa Relprevv. Significant changes include Latuda entering the marketplace. Seroquel should not be used with other drugs that may prolong the QT interval. Medication guides must be dispensed with Olanzapine and Quetiapine. Zyprexa Relprevv also requires a letter from the manufacturer regarding the patient care program and safe use of the product. At the last review for the oral agents, a motion for therapeutic alternatives passed unanimously. For the injectable agents, a motion for therapeutic alternatives to include one first and one second generation agent passed unanimously.

Dr. Brodsky noted that Zyprexa went generic last month.

DR. PAPPENHEIM MOVED THAT DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES FOR THE ORAL PREPARATION, AND ONE FIRST AND ONE SECOND GENERATION INJECTABLE SHOULD ALSO BE INCLUDED ON THE PDL. SECONDED BY DR. BERGESON.

Dr. Carlson noted that the larger states' formularies were very restrictive. He questioned if there was any state that was less restrictive than Alaska. Dr. Hope said Alaska has a very open PDL process. Every other state requires a hard prior authorization edit for non-preferred medications. The committee discussed the effectiveness of Alaska's PDL, the prior authorization requirement, the medically necessary clause, and the more restrictive formularies of private insurance companies.

THE MOTION PASSED UNANIMOUSLY.

7. Review of Long Acting Opioids (Red Category)

RUPA SHAH: A representative of Purdue Pharma discussed Buprenorphine (Butrans). Buprenorphine is a schedule 3 partial mu opioid agonist. It is also an agonist at the kappa receptor, the delta receptor, and a partial agonist at ORL1. Its clinical actions result from binding two opioid receptors. Buprenorphine behaves like a full mu agonist at analgesic doses. It is available on a transdermal system, which delivers Buprenorphine over seven days. It is indicated for the management of moderate to severe chronic pain in patients who require continuous opioid analgesia for an extended period. It is not indicated for the treatment of addiction. It's labeling includes a boxed warning describing a potential for abuse, proper patient selection, and limitations of use. Several studies and their outcomes were reviewed. I encourage you to review the adverse events, contraindications, warnings and precautions, and the full prescribing information. When initiating Buprenorphine, proper patient selection, consideration for all relevant product safety information, and other elements of prescribing

information are essential. The dosage forms were reviewed. Respiratory depression is a chief hazard and Buprenorphine may cause somnolence, dizziness, alterations in judgment, and alterations in levels of consciousness including coma. Butrans is the first Buprenorphine transdermal product approved for moderate to severe chronic pain for patients who meet the outlined criteria. We are requested that Butrans be included on the PDL.

In response to Dr. Demain, Ms. Shah said Butrans has been studied in patients who are both opioid naive and opioid experienced. When thinking about transdermal systems, the Fentanyl transdermal system is for a specific patient population than Butrans. The dosing range in which they require pain management is lower with Butrans than with Fentanyl.

In response to Dr. Hope, Ms. Shah said the proper patient for Butrans therapy is one who requires treatment with an opioid of less than 80 milligrams per day or oral Morphine equivalent. Patients who require more would not be an appropriate Butrans candidate.

LAURA LITZENBERGER: A representative of Janssen Scientific Affairs discussed Nucynta ER, which is a twice a day version of Nucynta IR. Several studies and their outcomes were reviewed. Nucynta ER is formulated in a tamper resistant formulation. It is a C2 medication, which can be still be abused, but it is more difficult to crush and turns into a gel if mixed with water to make it more difficult to inject.

DAN WOMER: A representative with Covidien, discussed Hydromorphone ER (Exalgo). Exalgo is an opioid agonist indicated for once daily administration for the management of moderate to severe pain in opioid tolerant patients requiring continuous opioid analgesia for an extended period. It is an extended release formulation of Hydromorphone and is not intended for use as an as-needed analgesic. It is available in 8, 12 and 15 milligrams. There is no effect of food or alcohol on the pharmacokinetic profile of Exalgo. At clinically relevant concentrations, there is little potential to inhibit activity of the following subtypes of the P450 system, 1A2, 2C9, 2C19, 2D6, and 3A4. The advantage to the delivery system is that plasma concentrations from Exalgo reach a broad, relatively flat plateau within six to eight hours after dosing and there is a steady state reached within three to four days after initiating therapy. It has been specifically designed to achieve a controlled and constant delivery of medication from two to 18 hours after administration, allowing for continuous elevated plasma concentrations over the 24-hour dose. The delivery system is a hard shell, which helps mitigate tampering with the drug. It also uses a variety of other ingredients that turns into a very viscous solution that makes it difficult to be brought into a syringe or snorted. Exalgo has an extensive risk evaluation mitigation strategy (REMS) in place. The intent of the class-wide REMS is to ensure that the therapeutic benefits of extended release opioid formulations continue to outweigh the risks, particularly addiction and unintended overdose and death resulting from inappropriate prescribing and misuse. This REMS program is voluntary for the prescribers. We believe it would be advantageous to have Exalgo included on the PDL.

Dr. Pritchard gave the Magellen presentation on Long Acting Opioids. Two letters from Fireweed Health Care and AA Spine Clinic asking that Nucynta ER be included on the PDL were read into the record. When properly used, long-acting opioids can decrease dosing frequency, decrease adverse effects, and increase consistent pain control. These agents are the drugs of choice for moderate to severe pain. Serious respiratory depression can occur at any time during use, but it usually occurs within the first 24 to 72 hours after initiation or increase in dose. Doses should be tapered gradually to

prevent withdrawal signs and symptoms. Buprenorphine transdermal, Hydromorphone ER, Oxycodone ER, and Morphine ER, and now Trazone combo, all participate in REMS requiring a medication guide be dispensed. In October, there were 744 claims: 31% for Oxycotin, 19% for Morphine Sulfate, 14% for Fentanyl. At the last review and for Tramadol ER, a motion for therapeutic alternatives passed unanimously. For the long-acting opioids, a motion for class effect to include Methadone in one transdermal preparation passed unanimously.

It was noted that the two most utilized drugs were not on the PDL. Dr. Hope said he had some concerns about Methadone was surprised by its utilization. The vast majority of the drugs require prior authorization, with the exception of the long-acting Tramadals. Dr. Demain was concerned that 75% of the drugs utilized in this class were not preferred so the retail price was being paid for them. Dr. Hope discussed the bidding process, which varies from drug to drug and manufacturer to manufacturer. The committee discussed why Methadone had such high utilization. Dr. Pritchard said most states do not allow Methadone to be used as a pain medication, but it seems to be a preferred item in Alaska. The committee discussed the abuse of this class. Methadone and Fentanyl appear to be the most abused.

DR. PHILLIPS MOVED A CLASS EFFECT TO INCLUDE ONE TRANSDERMAL PREPARATION. SECONDED BY DR. DEMAIN. THE MOTION PASSED WITH FOUR OPPOSED.

8. Re-Review of Steroids, Topical Very High Potency (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Steroids, Topical Very High Potency. These are used for a variety of inflammatory skin conditions. Very high products are available as shampoo, lotion, solution, cream, spray, gel, and ointment. They are indicated for the relief of inflammatory pruritic corticosteroid-responsive dermatoses, moderate to severe scalp psoriasis, and moderate to severe plaque psoriasis affecting up to 20% of body surface area. Psoriasis requires lifelong therapy to control signs and symptoms. Topical steroids are categorized based on anti-inflammatory activity. General adverse effects across all products can include burning, itching, dryness, and hypo-pigmentation, among others. All topical corticosteroid products are pregnancy category C. Pediatric populations are more susceptible to higher incidents of steroid induced HPA axis suppression in Cushing's syndrome due to a larger skin surface area to body weight ratio. Potency selection should be based on the severity of disease, body surface area, and body part affects, intended duration of therapy, and the age of the patient. In October, there were 55 claims: 75% for Cobetasol Propionate and 18% for Clobex. This is a new category so there was no previous discussion.

MR. GREEAR MOVED A CLASS EFFECT. SECONDED BY DR. MCCORMICK.

Dr. Demain felt that Cobetasol should be included in the motion since it is the most utilized drug. Dr. Gardner said a formulation that could be used on the scalp should be included on the PDL.

THE MOTION PASSED WITH ONE OPPOSED.

9. Re-Review of Steroids, High Potency (Red Category)

Dr. Pritchard gave the Magellen presentation on Steroids, Topical High Potency. These are indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. In October, there were 415 claims: 86% for Triamcinolone Acetonide and 9.5% for Fluocinonide. This is a new category so there was no previous discussion.

DR. MCCORMICK MOVED A CLASS EFFECT. SECONDED BY MR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

10. Re-Review of Steroids, Topical Medium Potency (Red Category)

Dr. Pritchard gave the Magellen presentation on Steroids, Topical High Potency. These are indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp, atopic dermatitis, mild to moderate atopic dermatitis in ages 3 months to 18 years. Atopic dermatitis, also known as eczema, is a chronic inflammatory skin condition and commonly occurs in those with asthma and/or allergic rhinitis. It can occur at any age, but is usually diagnosed in children under the age of 5. In October, there were 127 claims: 21% for Mometasone Furoate, 53% for Hydrocortisone Valerate, and 14% for Fluticasone Propionate. This is a new category so there was no previous discussion.

DR. MCCORMICK MOVED A CLASS EFFECT. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

11. Re-Review of Steroids, Topical Low Potency (Red Category)

Dr. Pritchard gave the Magellen presentation on Steroids, Low Potency. These are indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, mild to moderate atopic dermatitis, seborrhea dermatitis of the scalp, and psoriasis of the scalp. In October, there were 171 claims: 79% for Hydrocortisone. This is a new category so there was no previous discussion.

DR. DEMAIN MOVED A CLASS EFFECT. SECONDED BY DR. GARDNER. THE MOTION PASSED UNANIMOUSLY.

Break from 9:45 a.m. to 10:01 a.m.

12. Re-review of Anticonvulsants 1st and 2nd Generation (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation Anticonvulsants 1st and 2nd Generation. Medications in this class have various indications including use in epilepsy, fibromyalgia, neuropathic pain, bipolar disorder, and migraine. They also have varied warnings, contraindications, and interactions. Almost every agent in the class is part of REMS and medication guides are to be given when the drugs are dispensed. The drugs are pregnancy category D and category C. The products have similar efficacy. There is no single product recommended over another. In October, there were 572 Carbamazepine

claims, 928 First Generation claims, and 2,536 Second Generation claims, for a total of 4,036 claims of anticonvulsants. Significant changes include Gralise tablets, Epitol tablets, and Potiga tables became available. Potiga is indicated for partial seizures. During clinical trials, it was associated with psychotic symptoms, confused state, and hallucinations. QT prolongation was also noted in healthy study subjects with Potiga. At the last review, a motion for therapeutic alternatives for the first generation agents passed unanimously. A motion for therapeutic alternatives, without preference, for the second generation agents passed unanimously.

Dr. Brodsky noted that Magellen combined the first and second generation anticonvulsants into a single class. In response to Dr. Pappenheim, Dr. Hope said the only anticonvulsants that required prior authorization would be due to a maximum cost exceeded to ensure that the claim is being submitted accurately.

DR. PAPPENHEIM MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON.

In response to Dr. Carlson, Dr. Pritchard said her utilization report showed the overall number of claims and not the diagnosis for which it was prescribed.

THE MOTION PASSED UNANIMOUSLY.

13. Re-Review of Sedative Hypnotics (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Sedative Hypnotics. Insomnia is divided into three types based on duration: transient is up to one week, short-term is one to six months, and chronic. The agents in this class have different MOAs, but the 2008 Treatment Guidelines do not distinguish among the agents. Drug selection should be individualized based on co-morbid conditions, side effect tolerance, and whether the insomnia results from initiation or maintenance of sleep. Doxepin, Rozerem, and Zolphidem products participate in REMS and a medication guide is required at time of dispensing. Use with other CNS depressants is cautioned with all agents in this class. Specialized formulations of Zolphidem do not have a significant clinical advantage over tablets. In October, there were 1,247 claims: 50% for Zolphidem Tartrate, 15% for Temazepam, and 12.7% for Zolphidem Tartrate ER. Significant changes include Doxepin and Zolpimist became available. Doxepin is a tricyclic antidepressant found to have sedative properties. It binds with high affinity to the H1 histamine receptor where it acts as an antagonist. It has about a three-hour duration of action. It should not be used in patients with untreated narrow angle glaucoma or severe urinary retention. It is available in tablet form and should not be taken within three hours of a meal. At the last review, a motion for therapeutic alternatives passed with one opposed.

DR. KILEY MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

14. Re-review of ADD/ADHD - Now Stimulants & Related Agents (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Stimulants and Related Agents. Agents in this class are used to treat ADHD, hyper somnolence, and obesity. Stimulants act by blocking the reuptake of norepinephrine and dopamine in the presynaptic neuron. Amphetamines tend to release newly synthesized dopamine while Methylphenidate causes the release of stored dopamine. Both types are available as racemic or single isomer products. Provigil and Nuvigil participate in REMS with medication guides and communication plans. Kapvay and Intuniv have FDA indications for the treatment of ADHD as an adjunct to stimulants. Both act as alpha-2A adrenergic receptor agonists. Both have dose dependent decreases in blood pressure and heart rate. Patient should be cautioned not to become dehydrated or over heated. These agents should not be abruptly discontinue, but tapered down slowly to avoid effects on blood pressure. In October, there were 2,410 claims: 17.3% for Methylphenidate ER, 12.5% for Dextroamphetamine, and 12.3% for Intuniv. Significant changes include Strattera, Provigil and Nuvigil now require dose adjustments in case of hepatic impairment. In the last review, a motion for therapeutic alternatives, to include at least one extended release and one non-stimulant formulation, passed unanimously.

DR. KILEY MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEASE ONE EXTENDED RELEASE AND ONE NON-STIMULANT FORMULATION. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

15. Re-review of Opioid Dependence (Blue Category)

ROCHELLE WAGNER: A representative of Alkermes discussed Vivitrol, a one monthly extended release formulation of Naltrexone. Vivitrol is administered by intramuscular injection by a health care professional. It should not be administered via IV or sub cue. Naltrexone, an opioid antagonist and blocker, is the active ingredient in Vivitrol. It is FDA approved for the prevention of relapse to opioid dependence following opioid detoxification as part of a program that includes psychosocial support. Opioid dependent patients must be opioid free for seven to 10 days prior to Vivitrol administration or there is a risk of precipitating withdrawal. Unlike Buprenorphine or Methadone, Vivitrol is non-narcotic and does not continue the physiological opioid dependent state. It is not a controlled substance and presents no potential for abuse or diversion since it has no street value. Vivitrol can also be used for the treatment of alcohol dependence. A study and its outcomes was reviewed. Vivitrol inherited the black box hepatic toxicity warning from Naltrexone. It is contraindicated in acute hepatitis or liver failure. The most common adverse events were reviewed. We encourage you to review the full prescribing information for complete safety information. Vivitrol is a safe and effective extended release, non-narcotic option for the prevention of relapsed opioid dependence, which is a very difficult population to treat.

In response to several questions, Ms. Wagner provided the following information. For patients with ongoing acute pain, it is recommended that an alternative form of non-narcotic pain relief be used. As with all chemical dependency, the time that a patient uses Vivitrol will be specific to an individual. Vivitrol is well tolerated and recent studies have shown that patients continue with the treatment much longer than with other available treatments. Follow through is about three months. However, over 700

patients have been treated for more than six months and 400 patients have been treated for over a year. Compliance is between 40 and 60%. In the study, about 600 patients were screened for a concurrent major depressive disorder or a different codependency, with about 60% of those patients being admitted into the study. Patients are at risk for respiratory arrest if they try to overcome the blockade, which is one of the warnings. In the years that Vivitrol has been available, one patient has overdosed. The differences in efficacy between oral Naltrexone and Vivitrol in chemical dependency was discussed.

Dr. Hope said there was no prior authorization through point of sale or J-code for Vivitrol.

Dr. Pritchard gave the Magellen presentation on Opioid Dependence. For opioid abuse, the available agents for detoxification include Buprenorphine, Naloxone, and Naltrexone. All exert action at the mu-receptor; Buprenorphine as an agonist and the others as antagonists. Both of the combination products, Suboxone and Vivitrol, participate in REMS with medication guides to be given at time of dispensing. All agents are pregnancy category C. In October, there were 311 claims: 43% for Suboxone Sublingual, 42% for Suboxone tablet, and 11% for Buprenorphine. At the last review, a motion for therapeutic alternatives passed with one opposed.

Dr. Pappenheim felt that the committee should consider dividing ongoing maintenance with partial agonists and treatment of chemical dependency with something other than a partial agonist. Suboxone is clearly a very different medication that is used to manage addiction, whereas Vivitrol is for abstinence.

Dr. Hope noted that Suboxone and Subutex, the Buprenorphine products, have a prior authorization requiring that physicians have the DEA number. Vivitrol does not have that prior authorization, because there is not the data X waiver requirement.

DR. PAPPENHEIM MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. KILEY. THE MOTION PASSED WITH THREE OPPOSED.

16. Re-review Other Antidepressants (Green Category)

Dr. Pritchard gave the Magellen presentation on Other Antidepressants. The drugs in this class either inhibit the reuptake of, or block the receptors of, one of more of the neurotransmitters dopamine, serotonin, and norepinephrine. All agents in this class are indicated for treatment of major depressive disorder and other indications vary. Bupropion, Trazodone ER, and Venlafaxine ER tablets participate in REMS and medication guides must be provided. SNRIs may be as effective as SSRIs, but tend to have more concerning adverse events. In October, there were 1,587 claims for the other category and 987 claims for SNRI for a total of 2,574 claims. The top three were 48% for Trazodone, 13% for Bupropion XL 150 milligrams, and Bupropion XL 300 milligrams. For the SNRIs there was 54% for Cymbalta and 25% for Venlafaxine HCL ER. Significant changes include false positive urine drug screens has happened with patients taking Bupropion, even following discontinuation of therapy. Use confirmatory test to distinguish between Bupropion and Amphetamines. Severe skin reactions have been reported with Deloxatine and therapy should be discontinued at first sign on blisters, peeling rashes or other signs of hypersensitivity. At the last review, a motion for therapeutic alternatives for

SNRIs, to include at least one Fibromyalgia medication, passed with one opposed. A motion for therapeutic alternatives for the others passed unanimously.

Dr. Hope reiterated that Magellen combined SSRIs and SNRIs into a single category.

DR. PHILLIPS MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PAPPENHEIM.

It was noted that last year's motion included an agent for fibromyalgia. Dr. Hope said the medically necessary clause could be utilized.

THE MOTION PASSED WITH ONE OPPOSED.

17. Re-review of H2RAs (Green Category)

Dr. Hope noted that the intent was to remove this category from the PDL, because all of the products were generic and inexpensive. The drugs would still be available, but it would be a non-managed class.

18. Re-review of NSAIDs (Green Category)

Dr. Pritchard gave the Magellen presentation on NSAIDs. In this class, Alaska reviews the COX-2 inhibitors Celecoxib and Meloxicam. The selective COX-2 inhibitors provide anti-inflammatory effects and analgesia, but do have cardiovascular concerns. In light of this, the American Heart Association recommended that they be used as a last resort for those patients with a history of, or a risk of, cardiovascular disease. In October, there were 321 claims: 58% for Celebrex and 38% for Meloxicam tablet. At the last review, a motion for class effect passed unanimously.

Dr. Hope said the previous category was COX-2, but is now NSAIDs. If the motion was for class effect, the PDL would not necessarily include a brand named COX-2 inhibitor. Dr. Bergeson said COX-2 inhibitors play a significant role for patients with aspirin sensitivity.

DR. CARLSON MOVED CLASS EFFECT TO INCLUDE AT LEAST ONE COX-2 DRUG. SECONDED BY DR. DEMAIN. THE MOTION PASSED WITH ONE OPPOSED.

19. Re-review of Growth Hormone (Green Category)

Dr. Pritchard gave the Magellen presentation on Growth Hormone. Growth hormone is administered by either IM or sub cue injection. Most products are given six to seven times per week. Treatment may decrease insulin sensitivity so monitor patients with diabetes for hyperglycemia during therapy. These agents are similar in safety and efficacy. In October, there were 17 claims. The significant changes are that cases of pancreatitis in both children and adult treatment with Somatropin have been reported. In the last review, a motion for class effect passed with one abstention.

Dr. Hope noted that all the drugs in this class required prior authorization.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. GARDNER. THE MOTION PASSED UNANIMOUSLY.

20. Re-review of Skeletal Muscle Relaxants (Green Category)

Dr. Pritchard gave the Magellen presentation on Skeletal Muscle Relaxants. Skeletal musical relaxants are indicated for the treatment of muscular pain or spasms from peripheral musculoskeletal conditions and spasticity from upper motor neuron syndromes. These are generally administered orally, but Baclofen has an intrathecally formulation and Orphenadrine has an IM formulation. The mechanism of action in the ADR profiles and efficacy varies among agents. In October, there were 1,457 claims: 48.6% for Cyclobenzaprine, 24% for Tizanidine, and 17% for Baclofen. At the last review, a motion for therapeutic alternatives passed unanimously.

DR. PAPPENHEIM MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.

21. Re-review of Urinary Tract Antispasmodics (Green Category)

Dr. Pritchard gave the Magellen presentation on Urinary Tract Antispasmodics. Overactive bladder is a chronic and debilitating syndrome characterized by urinary urgency and frequency. It occurs at about the same rate for women and men, but females experience urge incontinence more often than males. These medications exert their effect by their antagonistic effect of muscarinic receptors, thereby depressing both voluntary and involuntary bladder contractions. The medications in this class are considered therapeutically interchangeable with selection being based on individual requirements, tolerance, and response. In October, there were 350 claims. Significant changes are that angioedema has been reported with several of these agents. If it occurs, therapy should be discontinued. At the last review, a motion for class effect, with one long-acting agent to be included, passed unanimously.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

22. Re-review of Progestins Used for Cachexia (Green Category)

Dr. Pritchard gave the Magellen presentation on Progestins Used for Cachexia. Megestrol is used for Cachexia resulting from many conditions, even though the FDA indication is for anorexia and Cachexia for patients with AIDS. Megestrol is a synthetic derivative of Progesterone. The mechanism of action is unknown. Both products are pregnancy category X. In October, there were 6 claims. Significant changes include chronic use of this agent has been associated with new onset diabetes. At the last review, a motion for class effect passed unanimously.

MR. RILEY MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

23. Review Minutes from September 16, 2011, Meeting

The meeting minutes were adopted as presented.

24. Comments from Committee Members or Chair

Dr. Brodsky thanked everyone for their participation. The next meetings are scheduled for January 20 and April 20, 2012.

Dr. Hope said the PDL update was delayed due to the conversion to HIPPA 50-10, but will be available soon.

The committee discussed how the supplemental rebate system worked.

The committee talked about only accepting letters from Alaskan health care practitioners in the future. Dr. Hope suggested printing and distributing all of the letters, but not reading them into the record.

25. Adjourn

Without objection, the meeting adjourned at 10:51 a.m.